PRESS RELEASE

March 11, 2019

Saniona initiates Phase 2a Tesomet clinical study in hypothalamic obesity patients

- **First hypothalamic obesity patients recruited**
- **Complementary to Prader-Willi syndrome (PWS), for which Phase 2a data expected Q1 2019**
- **Prepare Tesomet for pivotal Phase 2/3 studies during 2019 and start such pivotal studies in 2020**

Saniona (OMX: SANION), a biotech company focused on the central nervous system and eating disorders, announced today that it has recruited the first patient in a Phase 2a clinical study of Tesomet to treat the rare eating disorder hypothalamic obesity. The trial comprises a total of up to 25 patients and is conducted at Rigshospitalet in Copenhagen, Denmark.

The purpose of this study is to investigate the overall safety and tolerability as well as effect on satiety, appetite and weight loss of Tesomet in patients with hypothalamic obesity.

“Hypothalamic obesity is an orphan indication and a severe disease, with no effective pharmacological treatment available today for these patients who have lost their ability to feel satiety. Due to its mode of action, Tesomet could provide substantial benefits to these patients, making this a very interesting and important study both for them and Saniona,” says Jørgen Drejer, CEO of Saniona.

In the exploratory randomized, double-blind, placebo-controlled study, patients will receive either Tesomet (tesofensine 0.5 mg + metoprolol 50 mg daily) or matching placebo (2:1 randomization) for 24 weeks followed by an open-label extension study where all patients will receive Tesomet for 24 weeks resulting in a total treatment period of 48 weeks. Saniona expects to report the results from the double-blind part of the study in Q4 2019 and the full study in H1 2020.

The primary endpoint is overall safety and tolerability, which will be judged from all safety data collected during the study including recorded adverse events, laboratory data, blood pressure and heart rate. The secondary endpoints examine Tesomet’s effects on: satiety and appetite; bodyweight; body composition; lipids and metabolic parameters; quality of life; and craving for sweet, salty and fatty foods.

Patients with hypothalamic obesity experience a similar loss of appetite control as those seen in patients with PWS, and hence this study will complement Saniona’s development plans in PWS. These two rare eating disorders have several characteristics in common, including clinical symptoms, clinical trial design, regulatory advantages from potential orphan drug designation, as well as fast time to market due to relative short and small clinical studies.

“We intend to initiate interactions with regulatory agencies about initiating pivotal Phase 2b/3 studies in PWS when the dose finding has been completed and in hypothalamic obesity if this study proves to be successful. Our overall objective is to prepare Tesomet for pivotal Phase 2/3 studies in at least one of these indications in 2019,” Jørgen Drejer adds.

For more information, please contact

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This information is such information as Saniona AB (publ) is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication, through the agency of the contact person set out above, at 08:00 a.m. CET on March 11, 2019.

About Saniona

Saniona is a research and development company focused on drugs for diseases of the central nervous system and eating disorders. The company has four programs in clinical development. Saniona intends to develop and commercialize treatments for orphan indications such as Prader-Willi syndrome and hypothalamic obesity on its own. The research is focused on ion channels and the company has a broad portfolio of research programs. Saniona has partnerships with Boehringer Ingelheim GmbH, Productos Medix, S.A de S.V and Cadent Therapeutics. Saniona is based in Copenhagen, Denmark, and the company's shares are listed at Nasdaq Stockholm Small Cap (OMX: SANION). Read more at www.saniona.com.

About Hypothalamic Obesity

The hypothalamus is a tiny part of the brain with a size being close to that of an almond. The hypothalamus controls important biological functions including body temperature, hunger and body weight.

Hypothalamic obesity is a rare disease that can occur from the growth or surgical removal of rare benign brain tumors and from other types of injury to the hypothalamus including stroke, brain trauma or radiation for cancer patients. The surgical removal of a rare brain tumor, craniopharyngioma, is the most common cause of hypothalamic obesity. Hypothalamic obesity is therefore sometimes also referred to as craniopharyngioma associated obesity.

A craniopharyngioma is a benign tumor, which most commonly affects children between 5-10 years old, though onset can sometimes occur during adulthood. Craniopharyngioma is also a rare disease with an estimated prevalence of 1:50,000 in the US. The treatment involves surgical removal of the tumor in almost all patients. The procedure can lead to complications, including damage to the hypothalamus resulting insatiable hunger and morbid obesity. A high frequency of hypothalamic obesity, between 30% and 77%, has been reported following treatment. Due to the Prader-Willi syndrome-like insatiable hunger, hypothalamic obesity is sometimes referred to as "acquired Prader-Willi syndrome". As in Prader-Willi syndrome, the condition reduces quality of life and there is no pharmacological treatment available today for these patients.